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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Kligerman

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Filed: Herewith

Previous Examiner: J. Witz

For: Composition and Method for Reducing Gastro-Intestinal Distress Due
to Alpha-D-Galactoside-Linked/Containing Sugars

Assistant Commissioner for Patents

Washington, D.C. 20231

Attention: Box Patent Application

PRELIMINARY AMENDMENT

Dear Sir:

Preliminary to calculation of the filing fees and examination of the above noted application, entrance of the following remarks and amendments into the record is respectfully requested.

In the Claims:

Please cancel Claims 1 to 6, 9, 11 and 13.

Please amend the following claims:

7.(amended) A method of reducing gastric distress in a human due to ingestion of solid food containing alpha-D-galactoside-linked sugars, comprising ingesting a composition of alpha-galactosidase and a non-toxic ingestible excipient for said alpha-galactosidase, said composition being in liquid form and containing alpha-galactosidase in an amount effective to hydrolyze the alpha-D-galactoside-linked

sugars in-vivo to their simplest absorbable constituents, the ingesting of the composition being contemporaneous with the ingestion of said solid food containing said sugars.

8.(amended) A method according to claim 7, wherein said alpha-galactosidase-containing composition is ingested during a time period from about ¼ hour before to about ¼ hour after ingestion of the solid food containing alpha-D-galactoside-linked sugars.

10.(amended) A method in accordance with claim 20, wherein said alpha-galactosidase composition is ingested in liquid form by combining the liquid with said solid food.

12.(amended) A method according to claim 20, wherein said alpha-galactosidase composition is ingested in liquid form separately from said food.

Please add the following claims:

14.(new) A method according to claim 20, wherein said alpha-galactosidase-containing composition is ingested during a time period from about ¼ hour before to about ¼ hour after ingestion of the solid food containing alpha-D-galactoside-linked sugars.

15.(new) The method according to claim 20, wherein said alpha-galactosidase composition is ingested during the ingestion of said solid food.

16.(new) The method according to claim 20, wherein said solid food is selected from the group consisting of fruits, vegetables and legumes.

17.(new) The method according to claim 20, wherein said alpha-galactosidase composition is poured onto or mixed with said solid food.

18.(new) The method according to claim 20, wherein said alpha-galactosidase composition further contains an agent for potentiating said alpha-galactosidase.

19.(new) A kit for reducing gastric distress in a human due to ingestion of solid food containing alpha-D-galactoside-linked sugars, comprising:

a) a composition containing alpha-galactosidase and a non-toxic ingestible excipient for said alpha-galactosidase, said composition being in liquid form and containing an amount of alpha-galactosidase effective to hydrolyze said sugars in vivo to their simplest absorbable constituents after mixing in the stomach of the mammals ingesting the food; and

b) instructions for ingesting the composition contemporaneously with the ingestion of the solid food containing said sugars.

20.(new) A method of reducing gastric distress in a human due to ingestion of solid food containing alpha-D-galactoside-linked sugars, comprising ingesting a composition of alpha-galactosidase and a non-toxic ingestible excipient for said alpha-galactosidase, said composition being in liquid or powder form and containing alpha-galactosidase in an amount effective to reduce such gastric distress, the ingesting of the composition being contemporaneous with the ingestion of said solid food containing said sugars.

21.(new) A method of reducing flatulence in dogs and cats due to ingestion of solid food containing alpha-D-galactoside-linked sugars, comprising ingesting a composition of alpha-galactosidase and a non-toxic ingestible excipient for said alpha-galactosidase, said composition being in liquid or powder form and containing alpha-galactosidase in an amount effective to reduce flatulence, the ingesting of the composition being contemporaneous with the ingestion of said solid food containing said sugars.

22.(new) A method according to claim 21, wherein said alpha-galactosidase-containing composition is ingested during a time period from about ¼ hour before to about ¼ hour after ingestion of the solid food containing alpha-D-galactoside-linked sugars.

23.(new) The method according to claim 21, wherein said alpha-galactosidase composition is ingested prior to the ingestion of said solid food.

24.(new) The method according to claim 21, wherein said alpha-galactosidase composition is ingested during the ingestion of said solid food.

25.(new) The method according to claim 22, wherein said solid food is selected from the group consisting of fruits, vegetables and legumes.

26.(new) The method according to claim 21, wherein said alpha-galactosidase composition is sprinkled or poured onto or mixed with said solid food.

27.(new) The method according to claim 21, wherein said alpha-galactosidase composition further contains an agent for potentiating said alpha-galactosidase.

REMARKS

Claims 7 to 8, 10, 12 and 14 to 29 are in the application. A marked version of the amended claims accompany this paper.

An abstract on a separate sheet of paper accompanies this request.

Applicant respectfully requests an interview with the Examiner prior to the mailing by the USPTO of an Office Action in this application. The Examiner is requested to please contact the undersigned at the number indicated below to discuss this matter further.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned at the number below. If any additional fees or charges are required by this paper the Commissioner is hereby authorized to charge Deposit account 19-2570 accordingly.

Respectfully submitted,



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MARKED UP VERSION OF CLAIMS TO SHOW CHANGES MADE

7.(amended) A method of reducing gastric distress in a human [mammals] due to ingestion of solid food containing alpha-D-galactoside-linked sugars, comprising ingesting a composition of alpha-galactosidase and a non-toxic ingestible excipient for said alpha-galactosidase, said composition being in liquid form and containing alpha-galactosidase in an amount effective to hydrolyze the alpha-D-galactoside-linked sugars in-vivo to their simplest absorbable constituents, the ingesting of the composition being contemporaneous with the ingestion of said solid food containing said sugars [contemporaneously with the ingestion of said food in an amount effective to hydrolyze the alpha-D-galactoside to D-galactose].

8.(amended) A method according to claim 7 wherein said[the] alpha-galactosidase-containing composition is ingested during a time period from about 1/4 hour before to about 1/4 hour after ingestion of the solid food containing alpha-D-galactoside-linked sugars[containing food].

10.(amended) A method in accordance with claim 20,[7] wherein said alpha-galactosidase composition is ingested in liquid form by combining the liquid [the form of powder combined] with said solid food.

12.(amended) A method according to claim 20,[7] wherein said alpha-galactosidase composition is ingested in liquid form separately from said food.